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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,052	11/13/2001	Melvin Levinson	58092-012 (SCVL-110)	2825

7590 06/10/2003  
McDermott, Will & Emery  
28 State Street  
Boston, MA 02109

EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/10/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Y.K

<b>Office Action Summary</b>	Application No. 10/008,052	Applicant(s) LEVINSON ET AL.	
	Examiner Paul A Roberts	Art Unit 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, drawn to method of effecting hemostasis, classified in class 606, subclass 215.
- II. Claims 1 and 37, drawn to a different method of effecting hemostasis, classified in class 606, subclass 215.
- III, Claims 1 and 38-40, drawn to a different method of effecting hemostasis, classified in class 606, subclass 215.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions would not be used together. Only one of the three methods would be applied at a given time to stop bleeding. Further the methods recite different limitations thus they have different modes of operation.

Because these inventions are distinct for the reasons given above and the search required for Groups I-III are different, restriction for examination purposes as indicated is proper.

This application contains different species of glucosamine combinations.

Applicant must elect a hemostat device with one of the below:

1. Poly-N-acetylglucosamine
2. Poly-D-Glucosamine.
3. Both compounds

During a telephone conversation with Mark Lappin on April 9, 2003 a provisional election was made without traverse to prosecute the invention of Group I with group 3, claims 1, 2, 5, 6, & 11-14. Written affirmation of this election was received. Claims 3, 4, 7-10, 15-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected -invention.

Following the written affirmation, the applicant amended, the claims April 09, 2003. In light of the preliminary amendment, the requirement for election of species is withdrawn. The requirement between groups I-III is still proper because the limitations for each group do not require the same search as the limitations for the other groups, would require the examiner to conduct three separate searches, and the inventions are patentably distinct from each other.

Currently claims 1-36 are pending and claims 37-40 are withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Economou US 3,811,438, in view of McDevit et al. 2003/0050589, in view of De Lucca et al 4,833,238.

1. Regarding claims 1-35, as admitted by the applicant in the specification, the method of applying pressure to a wound, maintaining the pressure on the wound, and removing the pressure on a wound is well known in the art. Further, said method comprising additionally applying a closure pad to the wound, maintaining the pressure on the wound via the closure pad, and then removing the closure pad is well known in the art. This procedure is followed anytime a bandage such as the one disclosed by Economou US 3,811,438 is applied to a wound. The Economou bandage is comprised of adhesive tape, a non-woven material. However, Economou does not disclose the use of glucosamines in the bandage. Chitosan can be used to produce various glucosamines such as poly-N-Acetylglucosamine and Poly-D-glucosamine '589 and '238. Glucosamines are beneficial to place in wounds. McDevit teaches, " For instance, cationic polymers can help clean wounds because they typically have a strong attraction for negatively charged bacteria and deleterious acidic byproducts. One example of a cationic polymer that is suitable for use in the present invention is chitosan (poly-N-acetylglucosamine, a derivative of chitin) or chitosan salts. Chitosan and its salts are natural biopolymers that can have both hemostatic and bacteriostatic properties. As a result, chitosan can help reduce bleeding and infection." Further McDevit teaches that an acetate salt of the glucosamine may be created and used in the bandage by heating the salt. McDevit states, "Chitosan salt solutions can be prepared by dissolving a desired concentration of chitosan in an aqueous solution of a desired acid. A chitosan salt solution can be dried by various methods including lyophilization, spray drying or by heating in an oven. The resulting chitosan salt can then be dissolved in water to form a

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chitosan solution. It is understood that a chitosan salt solution, for example chitosan acetate, does not imply a covalent attachment of chitosan to acetate, but rather comprises a solution containing the acetate salt of chitosan.” McDevit does not disclose the use of poly-D-glucosamine. De Lucca discloses the cationic polymer, poly-D-glucosamine can be made from chitosan. De Lucca states this in col. 2, 35-65. Since poly-D-glucosamine would have the same healing properties as poly-N-acetylglucosamine it can be used interchangeably or in conjunction with poly-N-acetylglucosamine. At the time of the invention it would have been obvious to combine the glucosamines (either as an acetate salt or in solution), poly-D-Glucosamine from De Lucca, and poly-N-acetylglucosamine from McDevit, with the bandage of Economou to improve the healing properties of the bandage, because, chitosans “help clean wounds because they typically have a strong attraction for negatively charged bacteria and deleterious acidic byproducts.”

2. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Economou device in view Lebovic US 6309369. Economou discloses all of claim 1. Economou does not disclose the length of time to maintain the bandage on the wound. Lebovic states a bandage should be continuously applied to a wound for about a day in col. 1, lines 5-25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the combined Economou US 3,811,438 to a wound for at least ten minutes because Lebovic teaches that a bandage should be changed once every 24 hours.

### *Conclusion*

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6423234 B1      Air and water purification using continuous breakpoint  
halogenation

US 5166187 A      Biomaterials with a base of mixtures of collagen, chitosan and  
glycosaminoglycans, process for preparing them and their application in human medicine

US 3969189 A      Cell wall-lysing complex enzymes and a process for the production  
thereof

US 3635818 A      Chitin and chitosan as chromatographic supports and adsorbents  
for collection of metal ions from organic and aqueous solutions and sea water

US 5836970 A      Hemostatic wound dressing


US 6167652 B1      Method for treating cotyledonous plants


US 6461635 B2      Method of forming a barrier on an epidermal surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

  
Paul Roberts  
April 28, 2003

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700